

Appl. No.: 10/030,974

Amendment dated April 7, 2005

Applicants' Request for Reconsideration of the Final Action mailed December 1, 2004

#### REMARKS

Claims 19-38 are currently pending in the subject application.

#### Amendment - New Claims 39 and 40

Entry of new, independent claim 39 is respectfully requested. In new claim 39, another preferred embodiment of the present invention is set forth which specifies that the crosslinker-free chitosan composition is allowed to stand for 10 minutes to 10 hours prior to drying. Support for new claim 39 can be found in the Specification at page 9, line 28, through page 10, line 5.

Entry of new independent claim 40 is also respectfully requested. New claim 40 is equivalent to pending claim 19, but states the process of steps (b) as "precipitating . . . by" instead of "combining . . . to precipitate" and" and the process of step (c) as "forming . . . by drying" instead of "drying . . . to form".

No new matter has been introduced by said new claims 39 and 40. A complete listing of all claims ever presented is included herein in accordance with 37 C.F.R. §1.121(c). Applicants submit that the requested amendment does not raise any new issues and that all claims are in condition for allowance. Thus, entry of the amendment is therefore proper under 37 C.F.R. §1.116. Accordingly, Applicants respectfully request entry of the amendment after final.

#### Double Patenting Rejection

In the Office Action, the Examiner rejects claims 19-23, 25, 26 and 29-37 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-25 and 28-37 of copending U.S. patent application number 10/030,933 (hereinafter referred to as "the copending application").

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Applicants note that claim 24, wherein the chitosan is a cationically derivatized chitosan, is not subject to the obviousness-type double patenting rejection. Accordingly, Applicants submit that independent claim 31 and its dependent claims 32-38 also should not be subject to the obviousness-type double patenting rejection. [In the office action of March 17, 2004, the Examiner specially reinstated the rejection under 35 USC §102(b) with respect to claims 24, 31 and 36, but did not apply the obviousness-type double patenting rejection to claim 24.]

While not necessarily agreeing with the Examiner that any of the instant claims are obvious in view of the claims of each of the copending application, in an effort to expedite prosecution, Applicants are submitting herewith a Terminal Disclaimer. Applicants respectfully submit that the accompanying Terminal Disclaimer is sufficient to overcome the Examiner's rejections under the judicially created doctrine of obviousness-type double patenting, and withdrawal of this rejection is therefore respectfully solicited.

Rejection under 35 USC §102(b)

In the Office Action, the Examiner maintains the rejection of claims 19-23, 25-28, 32-35 and 37-38 under 35 U.S.C. §102(b), as being anticipated by Japanese Patent Publication No. JP 01-062302 A (hereinafter referred to as "JP '302"). [Since all claims, i.e., pending claims 19-38 are listed as rejected, the Examiner is presumably maintaining the reinstated rejection of claim 24, 31 and 36 over JP '302 (English translation) under 35 U.S.C. §102(b) as well.]

In the Final Action, the examiner states:

"The instant claims as amended do not recite addition of the precipitant quickly. They just recite at a rate sufficient to precipitate chitosan such that a crosslinker free chitosan composition having physically entangled strands are formed. The '302 patent teaches that in the neutralization step one may slowly add the aqueous solution of the base. The examples in the '302 patent do not specify a rate of addition of the base either. Hence the addition of the base in the examples and description of the '302 patent is seen as being done at a rate sufficient to precipitate the chitosan having physically entangled strands." (Emphasis added.)

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*Applicants submit that the plain meaning of the disclosure of JP '302 is contrary to what is "seen" by the Examiner.*

The following is stated in the English translation of JP '302:

On page 1, immediately under the heading "Detailed explanation of the invention":

"This invention pertains to a type of chitosan salt that is soluble in water in the neutral region, and its manufacturing method." (Emphasis added)

On page 2, the last paragraph under the heading "Problem to be solved by the invention":

"Consequently, there is a high demand for the development of a type of chitosan salt that is water-soluble in the neutral region so as to expand the application range of chitosan and to improve its stability." (Emphasis added)

On page 2, the second and third sentences in the first paragraph under the heading "Means for solving the problems":

"As a result of this research work, it was found that when sodium hydroxide, ammonium hydroxide, or another alkali is added into an acidic aqueous solution of chitosan, gelling takes place, and neutralization cannot be realized. However, when a carbonate salt is added, neutralization can be realized, and a neutral aqueous solution of chitosan can be obtained." (Emphasis added)

On page 3, in the last paragraph under the heading "Means for solving the problems":

"For the water-soluble chitosan salt of this invention prepared above, said neutral solution can be used as is in the fields of food, cosmetics, etc. However, it is preferred that the aqueous solution be freeze dried to form a powder, which is dissolved to form an aqueous solution for use." (Emphasis added)

In Application Example 1: "The obtained white colloidal solution was freeze dried to form a white powder. The powder was dissolved in water at a concentration of 0.5-4%, forming a clear aqueous solution." (Emphasis added)

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In Application Example 2: "05. g of Flownack N . . . ,forming a clear solution with pH 7.0."  
(Emphasis added.)

In Application Example 3:

"Then, 3g of calcium carbonate powder, forming a semi-transparent solution with pH 6.45."

The obtained solution was coated on wood, followed by drying, forming a nice coating film." (Emphasis added.)

In Application Example 4: "Then, A 5% NaHCO<sub>3</sub> aqueous solution was added to form a semi-transparent colloidal solution with pH 7.0." (Emphasis added.)

The Comparative Example, on the other hand, shows that, in the presence of NaOH, a precipitate was obtained instead of the desired solution, as follows:

"6.0 g of Flownack C were dispersed in 200 mL of water. 10.8 g of 50% lactic acid were added to form an acidic aqueous solution of chitosan. After adding 50 mL of 5% solution of NaHCO<sub>3</sub>, 47 mL of 2% NaOH were added, forming a white insoluble precipitate with pH 7.5. It was impossible to obtain a homogeneous colloidal solution." (Emphasis added.) [The precipitate is not characterized or dried.]

Thus, it is clear that only when the neutralization was attempted in the presence of NaOH did a precipitate form. In all other instances (i.e., where the carbonate alone was used for the neutralization step) a "solution" was formed. Thus, the present Applicants' step.(b), wherein a precipitant is combined with the aqueous mixture in an amount and at a rate sufficient to precipitate the chitosan such that a crosslinker-free chitosan composition having physically entangled strands of the chitosan is formed, *is in fact different from JP '302's "neutralization" step.*

Additionally, the Examiner is ignoring the words "to form a crosslinker-free three-dimensional structure" in present Applicants' drying step (c). In JP '302 the chitosan solution obtained in the

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neutralization step is either used directly. i.e., as a solution, or it is freeze dried as a powder. If it is freeze dried, the resulting powder is reconstituted as a solution. As noted above, in Application Example 3 of JP '302, "The obtained solution was coated on wood, followed by drying, forming a nice coating film." *Thus, there is no direct or inherent information in JP '302 justifying a conclusion that its drying step does or can lead to the formation of a three dimensional structure as is required in step (c) of Applicants' claim 19.*

For these reasons, Applicants respectfully request withdrawal of the rejection of claims 19-38 under 35 USC §102(b) and allowance of the application.

Respectfully submitted,

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4/7/05

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